



## MARYLAND DEPARTMENT OF THE ENVIRONMENT

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Deputy Secretary

March 10, 2010

The Honorable Maggie L. McIntosh, Chairman  
Environmental Matters Committee  
House Office Building, Room 251  
6 Bladen Street  
Annapolis, MD 21401-1991

Re: House Bill 648 – Environment – Drug Stewardship Program; House Bill 649 – Environment –  
Pharmaceutical Disposal Act

Dear Chairman McIntosh and Committee Members:

The Maryland Department of the Environment (MDE or “the Department”) has reviewed two (2) bills related to pharmaceutical disposal: House Bill 648 entitled *Environment – Drug Stewardship Program*, and House Bill 649 entitled *Environment – Pharmaceutical Disposal Act*. We would like to express our support for the overall objectives of take back programs and the proper collection, transportation, management, and disposal of unwanted drugs, while opposing the bills due to the resource burden they place on MDE.

HB 648 would create a new Drug Stewardship Program and would require, beginning January 1, 2012, a manufacturer of prescription, nonprescription, and veterinary drugs in any form, excluding vitamins or herbal-based remedies, who sells or offers drugs for sale in the State, to operate a drug stewardship program for the collection, transportation, and disposal of unwanted drugs. Under this bill, MDE’s responsibilities would include reviewing 230 or more manufacturers’ proposed stewardship programs for compliance and program updates every 4 years, to establish mandated performance standards and adopt regulations to implement the program. The Department’s costs under this bill would be over \$125,000 per year for 4 additional staff, supplies, equipment, and training.

A new Drug Stewardship Fund in the Department would be established to be used only for the purpose of covering the cost of carrying out the responsibilities of the Department under the new Program. It is estimated that there are 230 or more manufacturers that may sell drugs in Maryland. Fees of approximately \$544 per manufacturer would be required to cover MDE’s costs in the first year of the new Program. Overseas manufacturers and noncompliant manufacturers could prove difficult to motivate to comply and pay the established fees, resulting in the Department’s costs not being completely covered.

The bill allows the drug manufacturers to join together to form take back programs and requires manufacturers to take back all manufacturers' covered drugs. However, the broad definitions in the bill seem to encompass even some personal care products, such as antibacterial soaps and other antibacterial products. In its broadest reading, it could include toothpaste and mouthwashes as substances for the prevention of gum disease or sunscreens for the prevention of skin cancer. Further, the bill provides that component substances would also be considered drugs. Therefore, manufacturers of inactive ingredients in drugs, such as dyes, gums, celluloses, and other fillers would be included in the scope of the law, making it difficult for MDE to regulate this large universe of manufacturers. In addition, this overly broad definition of drug could create confusion for our citizens, as to which "drugs" are the most hazardous.

Also, it is unlikely that all manufacturers will form a single take back program with the same procedures for taking back drugs, perhaps adding to citizens' confusion as they determine how to manage their unwanted drugs. Manufacturers would be required to pay all the costs of the take back programs and carefully track the drugs they take back. Depending on the methods chosen by the manufacturers for the take back programs, there could be health and safety issues related to storage of large quantities of controlled drugs awaiting shipment to processing/management facilities.

HB 648 is well intentioned in trying to reduce or eliminate drug ingredients from reaching the waters of the State. However, the bill makes no distinctions between what drugs, or components of drugs, are more harmful to human or animal health or the environment and which are benign. The law would, therefore, be extremely difficult to enforce and would impose a resource burden on the Department.

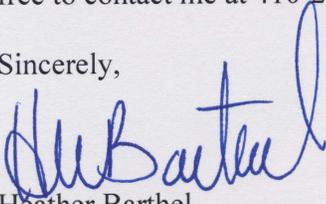
HB 649 would prohibit health care facilities from disposing of unused medication into a wastewater system and charges MDE with enforcing this law. It provides for \$500 fines for violation. The proposed fines are small compared to many other environmental laws that MDE enforces.

In addition, this bill would require MDE to conduct regulatory oversight over a very large regulated community. Virtually every health care facility is covered. MDE's Water Management Administration's Compliance Program would need to conduct inspections, respond to complaints, and take enforcement actions for the new law. According to the 2002 Economic Census, which is the latest available from the U.S. Census Bureau, Maryland has a total of 13,923 health care and social assistance establishments and 40,234 pharmacies. It is estimated that 2 new environmental compliance specialist positions would be needed to perform inspections. This bill would create a major new initiative that adds significantly to the duties and responsibilities of the Department.

HB 649 has a worthwhile focus on drugs discarded in the nonresidential setting, since these sources are expected to be significant contributors to the discarded drug burden. It is unknown if such a measure would translate into meaningful behavior change at the level of the health care facility, or how many compliance investigations and enforcement actions would need to occur. Enforcement may come down to the credibility of verbal reports of noncompliance. Whether people would report things would remain to be seen.

To summarize, both HB 648 and HB 649 have merit in protecting Maryland's water environment. However, both bills present a resource burden and enforcement difficulty for the Department to implement. Thank you for your consideration. We will continue to monitor both House Bills 648 and 649 during the Committee's deliberations, and I am available to answer any questions you may have. Please feel free to contact me at 410-260-6301 or by e-mail at [hbarthel@mde.state.md.us](mailto:hbarthel@mde.state.md.us) if I can be of assistance.

Sincerely,



Heather Barthel  
Director of Legislation and Policy

cc: The Honorable Ben Barnes  
Shari T. Wilson, Secretary  
Lisa Nissley, Legislative Liaison/Environmental Justice Coordinator  
Horacio Tablada, MDE, Director, Land Management Administration  
Jay G. Sakai, MDE, Director, Water Management Administration